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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,133	01/12/2007	Peter Dorff	101158-1P US	8759

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EXAMINER	
DESAI, RITA J	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
07/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,133	DORFF ET AL.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2010*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *12-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants request for rejoinder of group I and III has been considered by the examiner and she has agreed to rejoin them.

The restriction between group I and II has been withdrawn.

The restriction is now made FINAL.

Claims 1-11 are under consideration.

Response to the arguments:-

Applicants argue that Tracy et al discloses the compound in the most generic terms. There would be no motivation to pick and chose a specific compound. This is not convincing . see claim 12 which teaches the specific phenyl substituted compound. Roger teaches the radio labeled compounds for the non-invasive diagnosis of diseases or disorders, such as Alzheimer's, schizophrenia, etc.

Applicants argue that the compounds do not have a carbonyl group is also not convincing, the activity is the same, the compounds have a very close similarity in structure and applicants invention of using them as a diagnostic compound by having a radiolabeled group for R1, is an obvious variation as it is well known to have a radiolabeled atom in the structure.

Applicants have not argued the natural abundance of radilabelled compounds..

As the examiner has expanded the restriction and included group III , she is adding the Phillip et al.reference to teach other heteroaryl , see 5'-(3-pyridyl)spiro[1-azabicyclo[2.2.2]octane-3,2'-(3'H)-furo[2,3-b]pyridine]. in claim 8.

Phillips et al. (US 6,110,914) discloses potent ligands selective for o~-7 nAChR's and used for the treatment of Alzheimer's disease, schizophrenia, etc. (column 1, lines 12-13 and 17-21; column 18, lines 3 and 5). The compounds (below) may contain D, G and A which are C(R2), C($R^{3)}$ and C($R^{4)}$ respectively where R^{2-4} may be C14alkyl, aryl (phenyl) optionally substituted with a halogen, heteroaryl (pyridyl, pyrazinyl, etc.) optionally substituted with a halogen, or NR5R^6 where R5R^6 may be C1-4 alkyl, C(O)R^7 where R^7 is phenyl (column 1, lines 50+; column 2, lines 5-8,17,18,25-26,52 and 59). Y may be CH, N, or NO and W may be O, H2 or F2 (abstract). The compounds of the disclosure have binding affinities of less than 1000nM and have the advantage of being less toxic, more efficacious, longer acting, more potent, produce fewer side effects, are more easily absorbed and have a broad range of activity (column 19, lines 6-13).

Rogers et al. (US2004/0157878A1) discloses compounds of the type seen below where I* is ^{123}1 or ^{125}1 and azabicyclo is azabicyclo[2.2.2]octane or azabicyclo[2.2.1.]heptane (p3, column 1; p18, [0287]; p26, example 1). The compounds are of the disclosure exhibit high selectivity and selective affinity to c~-7 nAChR (p5, [0038]).

These compounds/pharmaceutical compositions (p13, [0225]; pl 5, [0276]) are useful for the medical therapy (pl, [0002]) or for the method of in vivo imaging of the relative

number and/or function of the o~-7 nAChR where the radioactively labeled compound is administered to a mammal (p15, [0268]) and detected by PET or SPECT (depending or the radiolabel) (p2, [0010], [0015] and [0017]). The compounds allow for the non-invasive diagnosis of diseases or disorders, such as Alzheimer's, schizophrenia, etc. (pl, [0006]; p2, [0017]). The compounds of the disclosure may be radiolabeled with isotopes, such as ^{11}C, ^{18}F, ^{99}rnTc, $^{123}1$ or $^{125}1$ (p4, [0033]; p13, [0227]).

Applicants have not argued the double patenting and it still stands.

New Grounds of Rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

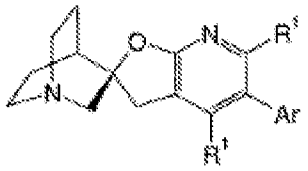
Claims 1-11 are rejected under 35 U.S.C. 103(a) (102(e) date)as being unpatentable over WO 2005000250 Pompers et al (others)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Applicants claims are drawn to

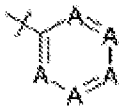
1. A compound in accord with formula I:



I

wherein:

Ar is a moiety formula II:



II

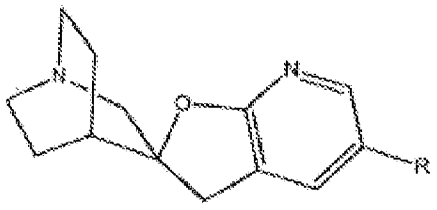
wherein:

A is independently at each occurrence CR^1 or N provided at least one A is R^1;

R^1 is independently at each occurrence H, C_1-C_6alkyl, or halogen, provided that at least one occurrence of R^1 comprises tritium or a halogen radioisotope.

Scope & Content of Prior Art MPEP 2141.01

On page 9, the reference clearly teaches the core and the radiolabeled compounds for diagnostic use.



IVa

wherein

R is N-C_{1-4}alkyl-N-benzylamino, N-C_{1-4}alkyl-N-benzoylamino, mono- and di-C_{1-4}alkylamino, or

R is phenyl, furyl, thienyl, pyridinyl, pyrimidinyl, pyrazinyl, imidazolyl, or oxazolyl, each of which is substituted with one or more substituents selected from halogen, hydroxy, amino, cyano, formyl, C_{1-4}alkyl, C_{2-4}alkenyl, C_{2-4}alkynyl, C_{1-4}alkoxy, C_{1-4}alkylthio, C_{1-4}haloalkyl, C_{1-4}haloalkoxy.

Certain preferred compounds of Formula III, IV, or IVa, include those compounds in which the R group comprises at least one radioactive isotope or more preferably one or more positron emitting radioactive isotopes. Yet other preferred compounds of Formula III, IV, or IVa include those compounds in which the R group comprises at least one radioactive isotope of carbon, fluorine, technetium, or iodine. Typically preferred radioactive isotopes of carbon, fluorine, technetium, and iodine, which are suitable for inclusion in the R group of compounds of Formula III, IV, or IVa include radioactive isotopes selected from ^{11}C, ^{18}F, ^{99}Tc, ^{123}I, ^{125}I, and ^{131}I.

Also see claim 16.

Difference is that it discloses a genus with species that would fall within the scope of the instant invention. Thus it would have been primafacie obvious to make the specific disclosed species of the claimed invention.

Conclusion

Claims 1-11 are rejected.

Claims 12-15 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rita J. Desai/
Primary Examiner, Art Unit 1625

July 11, 2010.